

EPA Jacket 69361-41




U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7504P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Registration
Number:

69361-41

Date of Issuance:

 **AUG 20 2013**

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance: **Unconditional**

Name of Pesticide Product:

Dicamba Technical Herbicide

Name and Address of Registrant (include ZIP Code):

Repar Corporation
P.O. Box 4321
Silver Spring, MD 201914

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is registered in accordance with FIFRA sec 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Make the following label revisions:
 - a. Add the EPA Registration Number 69361-41 to the label
 - b. Add an appropriate EPA Establishment Number to the label
 - c. Add appropriate Net Contents information to the label
 - d. Submit one copy of the final printed labeling for the record before you release the product for shipment.

If these requirements are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A copy of your label stamped "Accepted" is enclosed for your records.


The basic formulation CSF [dated March 6, 2013] of the product referred to above, submitted in connection with registration under the Federal Insecticide Fungicide, and Rodenticide Act is acceptable. The basic CSF will be added to your file.

If you have any questions, please contact Amaris Johnson at (703) 305-9542 or johnson.amaris@epa.gov.

Signature of Approving Official:

Kathryn V. Montague
Product Manager 23
Herbicide Branch
Registration Division (7505P)

Date:

 **AUG 20 2013**

Repar Corporation [Company Logo]
DICAMBA TECHNICAL HERBICIDE
 FOR MANUFACTURING PURPOSES ONLY

Active Ingredient:
 Dicamba (3,6-dichloro-Q-anisic acid) 98.3%
 Other Ingredients 1.7%
Total 100.0%

KEEP OUT OF REACH OF CHILDREN
DANGER

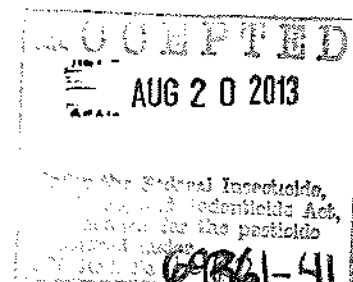
FIRST AID (Benzoic acid)	
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses if present, after the first 5 minutes, and then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER (Benzoic acid) Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information call: 1-(866)-359-5660	
NOTE TO PHYSICIAN Corrosive. Probable mucosal damage may contraindicate the use of gastric lavage. Causes irreversible eye damage.	

NET CONTENTS:

EPA Reg. No.:

EPA Est. No.:

Repar Corporation
 P. O. Box 4321 · Silver Spring, MD 20914



PRECAUTIONARY STATEMENTS

Hazards To Humans And Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, or skin, or on clothing. Avoid breathing dust. Wear goggles or face shield when handling.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only For Formulation Into A Herbicide For (1) The Following Use(s): Small Grains (Barley, Proso Millet, Oats, Rye, and Wheat), Corn, Sorghum, Sugarcane, Golf Course and Residential Lawns, Sod Farms, Pastures, Rangeland and Rights of Ways. (2) Uses For Which U.S. EPA Has Accepted the Required Data And/Or Citations Of Data That The Formulator Has Submitted In Support Of Registration; and (3) Uses For Experimental Purposes That Are In Compliance With U.S. EPA Regulations.

This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such use(s).

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

Container Disposal:

Nonrefillable Containers – Metal: Do not use or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by the State and Local authorities.

Fiber Drums with Liners: Do not use or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then offer for recycling if available, or dispose of liner in a sanitary landfill, or by incineration or, if allowed by State and Local authorities by burning. If burned stay out of smoke. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Paper Bags, Bulk Sacks: Do not reuse or refill bag/sack. Completely empty bag/sack by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then offer for recycling if available, or dispose of bag/sack in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Notice of Warranty and Disclaimer

Seller warrants that at the time of delivery the product in this container conforms to its chemical description contained hereon and is reasonably fit for its intended purpose only when used in accordance with proper manufacturing practices and procedures and under normal conditions of use. This is the only warranty made on this product. To the extent of applicable law seller expressly disclaims any implied warranties of merchantability or fitness for any purpose and, except as set forth above, any other express or implied warranties. Any damages arising from breach of warranty or negligence shall be limited to direct damages not exceeding the purchase price paid for this product by Buyer, and shall not include incidental or consequential damages such as, but not limited to, loss of profits or values. It is impossible to eliminate all risks inherently associated with the use of this product. To the extent of applicable law in no case shall Seller be liable for the consequential, special or indirect damages resulting from the use or handling of this product. The Buyer shall assume all such risks. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

MANDAVA ASSOCIATES, LLC

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS

6860 N Dallas Parkway, Suite 200, Plano, TX 75024

Telephone: (972) 265-7924 / Fax: (202)-223-0141 / E-MAIL: Madhu@Mandava.com / www.Mandava.com

Via FEDEX:

March 6, 2013

Document Processing Desk (WAIVER)
Herbicide Branch
Registration Division (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Kable Bo Davis
Team Leader (25)

Subject: Repar Corporation - EPA Number 69361
APPLICATION FOR NEW PRODUCT—"ME-TOO" FAST TRACK R300
Dicamba Technical Herbicide; Small Business Fee Waiver Exemption,
PRIA EPA Fee Category No.R300, CR No. 44

Dear Ms. Montague,

On behalf of Repar Corporation, we are submitting a "Me-Too" Registration Application for Dicamba Technical Herbicide. This registration application qualifies for an expedited review (Fast Track) as it is identical or substantially similar in composition, use, and labeling to [REDACTED]

Enclosed, please find the following materials in support of the application for registration of Dicamba Technical Herbicide:

- 1) Application for Pesticide Registration (EPA Form 8570-1)
- 2) Copy of EPA Payment of PRIA Fee
- 3) Copy of Small Business Fee Waiver Exemption Request
- 4) Formulator's Exemption Statement (EPA Form 8570-27)
- 5) Confidential Statement of Formula (EPA Form 8570-4)
- 6) Five (5) Copies of Draft Labeling

Please send to my attention the EPA Registration Notice and Stamped Approved Labels at the address listed below. We look forward to a quick approval of this application.

If you have any questions regarding this submission, please contact me at (972) 265-7924.

Madhu Mandava
Mandava Associates, LLC
Agent for Repar Corporation
Phone: (972) 265-7924
E-MAIL: Madhu@Mandava.com

E-MAIL: Madhu@Mandava.com

[illegible]

Please read instructions on reverse before completing form.

Form Approved

OMB No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 69361	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Dicamba Technical Herbicide	PM# 25	
5. Name and Address of Applicant (Include ZIP Code) Repar Corporation P. O. Box 4321 Silver Spring, MD 20914 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. [REDACTED] Product Name [REDACTED]	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New Product; Me-Too Registration; Fast Track: PRIA Category: R300, CR No. 44(Receipt Attached)
submitted fee: \$358.50; Small Business Fee Waiver Exemption
Please send all correspondence to Mandava Associates, L.L.C, 6860 N. Dallas Pkwy, Suite 200, Plano, TX 75024 Attn: Madhu Mandava
E-mail: madhu@mandava.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 kg, 55 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Madhu Mandava	Title Agent for Repar Corp.	Telephone No. (Include Area Code) 972-265-7924
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Repar Corporation	
4. Typed Name Madhu Mandava	5. Date March 6, 2013	

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 4/10/13


Experts In-Processing Signature: MP Date 4/16/13 Fee Paid: Yes

Division management contacted on issues No Yes Date

EPA Reg. Number: <u>69361-UR</u>		EPA Receipt Date: <u>4/10/13</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<u>100% repack</u>	X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)				X	
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				X	
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5					X
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

 100% repack, no inerts to review

Shackel Pass

FLG

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 11, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-477458
EPA File Symbol or Registration Number: 69361-UR
Product Name: DICAMBA TECHNICAL HERBICIDE
EPA Receipt Date: 10-Apr-2013
EPA Company Number: 69361
Company Name: REPAR CORP

REPAR CORP
PO BOX 4321
SILVER SPRING, MD 20914

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300
NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED) TO AN IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO DATA REVIEW ON ACUTE TOXICITY, EFFICACY OR CRP - ONLY PRODUCT CHEMISTRY DATA;CITE-ALL DATA CITATION, OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA, OR APPLICANT SUBMITS SPECIFIC AUTHORIZATION LETTER FROM DATA OWNER;CATEGORY ALSO INCLUDES 100% RE-PACKAGE OF REGISTERED END-USE OR MANUFACTURING-USE PRODUCT THAT REQUIRES NO DATA SUBMISSION NOR DATA MATRIX;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely, *Peressa Downs*
Front End Processing Staff
Information Technology & Resources Management Division

Similarity Clinic Screen Completed

Date: 4/25/13

Jacket #: 69361-UR

Actions Done:

Acute Toxicity Review: COMPLETED - IN JACKET

Acute Toxicity Language for Label: IN REVIEW

Product Chemistry Review: 100% REPACK OF

Transfer This Jacket To:

PM 25, KABLE DAVIS

Really on team 03

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

April 19, 2013

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA Reg. No.: 69361-UR
PC Code: 029801
D.P Code. 411182
Decision No. 477485

From: Masih Hashim, Toxicologist
Technical Review Branch
Registration Division (7505P) *TH*

To: John Redden, Acting Branch Chief-TRB
/Kable Davis RM 25, Herbicide Branch
Registration Division (7505P)

Applicant: Repar Corporation
Silver Spring, MD 20814

FORMULATION FROM EPA Reg. No. 69361- 41 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Dicamba	98.3
<u>Inert Ingredient(s)/ impurities ..</u>	<u>1.7</u>
Total	100.0%

#69361-UR (P.C. Code 411182)

BACKGROUND: The registrant has asked for a re-pak and cited data from Reg. No. # [REDACTED] to support the proposed product #69361-UR. [REDACTED]
[REDACTED]
[REDACTED]

RECOMMENDATIONS: After examining the CSF's for the cited and proposed products, the Agency has no objection to bridging data between the two (substantially similar) products. Both the products have DANGER as the Signal Word (due to eye toxicity). The CSF dated 3-6-13 should be approved by Product Chemistry.

The acute toxicity profile for the File Symbol #69361-UR is as follows:

Acute Oral	III	Cited (LD ₅₀ > 2000 mg/kg)
Acute Dermal	III	Cited (LD ₅₀ >2000 mg/kg)
Acute Inhalation	III	Cited (LC ₅₀ >1.18 mg/L)
Primary Eye	I	Cited
Primary Dermal	IV	Cited
Skin sensitization	not a sensitizer	Cited

NOTE: The acute toxicity requirements have been satisfied for the subject product.

Label

PRODUCT ID #: 069361-00041

PRODUCT NAME: Dicamba Technical Herbicide

PRECAUTIONARY STATEMENTS

SIGNAL WORD: DANGER

SPANISH SIGNAL WORD: PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. Child Resistant Packaging Required.

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin. Harmful if inhaled. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using toilet. Remove and wash contaminated clothing before reuse. Avoid contact with skin, eyes or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Avoid breathing spray mist. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

Page 2 of 3

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Note to PM/CRM/Registrant: The proposed label should contain a **Note to Physician** which addresses the category I Primary Eye Irritant toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

21-Day Screen Completed by
Contractor

21-Day Expires on 5/1/13

Jacket # 69361-UR

MRID# n/A

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Steve Schauble

United States


 Environmental Protection Agency
 Washington, DC 20460

Formulator's Exemption Statement
 (40 CFR 152.85)
Applicant's Name and Address
 Repar Corporation
 P. O. Box 4321
 Silver Spring, MD 20914
EPA File Symbol/Registration Number

69361-

Product Name

Dicamba Technical Herbicide

Date of Confidential Statement of Formula (EPA Form 8570-4)

March 6, 2013

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Dicamba (3,6-dichloro-Q-anisic acid)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

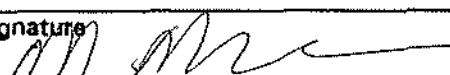
(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.**Source**

Active Ingredient	Product Name	Registration Number
Dicamba (3,6-dichloro-Q-anisic acid)	[REDACTED]	[REDACTED]
Signature: 		
Name and Title: Madhu Mandava Agent for Repar Corporation		Date: 03/06/2013

Receipt for Section 3													
S: 933518		Resubmission: <input type="radio"/> Yes <input checked="" type="radio"/> No											
Regulatory Type:	Product Registration - Section 3	Fee For Service:	<input checked="" type="radio"/> Yes <input type="radio"/> No	<div>Print Letter</div> <div>Enter More Information</div> <div>Tracking</div>									
Application Type:	New Registration	Billable:	<input checked="" type="radio"/> Yes <input type="radio"/> No										
Company:	69361 REPAR CORP	V											
Risk Manager:	Registration Division, Risk Management Team 25												
Product #:	69361-UR	Product Name:	DICAMBA TECHNICAL HERBICIDE										
Overrides:													
Me Too Section3:		Me Too Product Name:											
Application Date:	07-Apr-2013	OPP Rec'd Date:	10-Apr-2013	<table border="1"> <thead> <tr> <th>Receipt Content</th> <th>Des</th> </tr> </thead> <tbody> <tr> <td>CSF</td> <td></td> </tr> <tr> <td>Paper Label</td> <td></td> </tr> <tr> <td colspan="2"> <div><</div> <div></div> <div>></div> </td> </tr> </tbody> </table>		Receipt Content	Des	CSF		Paper Label		<div><</div> <div></div> <div>></div>	
Receipt Content	Des												
CSF													
Paper Label													
<div><</div> <div></div> <div>></div>													
Front End Date:	11-Apr-2013	Risk Manager Send Date:											
FFS Due Date:		Negotiated Due Date:											
OPP Target Date:													
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>	<div>View/Edit</div>									
Receipt Description: NEW PRODUCT ME-TOO REGISTRATION													
Form A:	<input type="checkbox"/>	Signature Date:		Form B:	<input type="checkbox"/>								
		Signature Date:											

Product ingredient source information may be entitled to confidential treatment

Fee for Service

W
{9335185~

This package includes the following

- New Registration
- Amendment

- ☐ Studies? ☒ Fee Waiver?
- ☐ volpay % Reduction: 75%

for Division

- AD
- BPPD
- RD

Risk Mgr. 25

Receipt No.

S- 933518

EPA File Symbol/Reg. No.

69361-UR

Pin-Punch Date:

4/10/2013

- ☐ This item is NOT subject to FFS action.

Action Code:

Requested: R300

Granted: R300 (w)

Amount Due: \$ 1434⁰⁰

100% repack

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: K. Manly

Date: 4/11/13

Remarks:

Sim Clinic - needs tox profile

Online Payment
Step 3: Confirm Payment

1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information**Application Name:** PRIA Service Fees**Pay.gov Tracking ID:** 25A9FCHJ**Agency Tracking ID:** 74433671733**Transaction Date and Time:** 04/09/2013 21:56 EDT**Payment Summary****Address Information****Account Holder Name:** Madhu
Mandava
15404 Tindlay**Billing Address:** Street**Billing Address**

2:

City: Silver Spring**State / Province:** MD**Zip / Postal Code:** 20905**Country:** USA**Account Information****Card Type:** American
Express**Card Number:** *****2011**Decision****Number:****Registration****Number:**

Repar

Company Name: Corporation**Company Number:** 69361**Action Code:****Payment Information****Payment Amount:** \$358.50**Transaction Date** 04/09/2013
and Time: 21:56 EDT

R 300 and 301

100% identical (repack): YES or NO (circle one)

{If **yes**, it's a 100% repack then product chemistry, acute toxicity and efficacy data are not required}

Data on Group A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition		
830.1600	Description of materials used to produce the product		
830.1650	Description of formulation process		
830.1670	Discussion on the formation of impurities		
830.1700	Preliminary analysis		
830.1750	Certified limits (158.345)		
830.1800	Enforcement analytical method		

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color		
830.6303	Physical State		
830.6304	Odor		
830.6314	Oxidation/Reduction (Chemical incompatibility)		
830.6315	Flammability		
830.6316	Explosibility		
830.6317	Storage stability		
830.6319	Miscibility		
830.6320	Corrosion Characteristics		
830.6321	Dielectric Breakdown voltage		
830.7000	pH		
830.7100	Viscosity		
830.7300	Density		

R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)		
870.1200	Acute Dermal (LD50)		
870.1300	Acute Inhalation (LC50)		
870.2400	Acute Eye Irritation		
870.2500	Acute Dermal Irritation		
870.2600	Dermal Sensitization		

Efficacy – which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants			
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments			
810.3300	Treatments to Control Pests of Humans and Pets			
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments			
810.3500	Premises Treatments			
810.3600	Structural Treatments			
810.3800	Methods for Efficacy Testing of Termite Baits			

Confidential Statement of Formula may be entitled to confidential treatment